# Exhibit 4

Siri | Glimstad

sirillp.com | NEW YORK | LOS ANGELES | MIAMI | PHOENIX
DETROIT | AUSTIN | CHARLOTTE | WASHINGTON D.C.

**CDC FREEDOM OF INFORMATION ACT APPEAL**

**SUBMITTED VIA ONLINE PORTAL** December 13, 2024

Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue
Suite 729H
Washington, D.C. 20201

Re: *Appeal of FOIA Request #25-00165-FOIA (IR#1151E)*

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("**ICAN**") and Mississippi Medical Professionals for Informed Consent ("**MMPIC**"). On behalf of ICAN and MMPIC, on November 1, 2024, we submitted the following request for records ("**FOIA Request**") to Centers for Disease Control and Prevention ("**Agency**") pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**"):

> All emails in which Tom Shimabukuro responded to the email provided at Attachment A; and all emails in which Walter Orenstein and/or Tom Shimabukuro forwarded the email provided at Attachment A.

(**Attachment 1**.)

The request was acknowledged and assigned FOIA Request #25-00165-FOIA on November 4, 2024. (**Attachment 2**.)

On November 5, 2024, the Agency responded to the FOIA Request ("**Final Response**"). ICAN writes now to appeal the Final Response. The letter stated in relevant part:

> Electronic searches were conducted for records responsive to your request. A search of our records failed to reveal any documents pertaining to your request. Additionally, Dr. Orenstein left CDC in 2007, so his emails could not be searched for this request, nor would they have been responsive, given the timeline of your request.

(**Attachment 3**.)

## I. ARGUMENT

For the reasons set forth below, ICAN appeals the Agency's Final Response:

### A. Adequacy of Search

#### *1. Legal Standard*

The Agency has failed to conduct an adequate search of the requested records. An agency's search is adequate only if it is reasonably calculated to uncover all relevant documents. *Valencia-Lucena v. United States Coast Guard*, 180 F.3d 325 (D.C. Cir. 1999). "An agency fulfills its obligations under FOIA if it can demonstrate *beyond material doubt* that its search was reasonably calculated to uncover all relevant documents." *Defs. of Wildlife v. United States Border Patrol,* 623 F. Supp. 2d 83, 91 (D.D.C. 2009) (internal quotation marks omitted) (emphasis added). To satisfy its FOIA obligations, an agency needs to adequately describe the scope and methods of its searches, which can reasonably be expected to uncover the records sought and demonstrate that the places most likely to contain responsive materials were searched. *Davidson v. E.P.A.*, 121 F. Supp. 2d 38, 39 (D.D.C. 2000). At a minimum, the Agency must specify "what records were searched, by whom, and through what process." *Steinberg v. U.S. Dep't of Justice*, 23 F.3d 548, 552 (D.C. Cir. 1994).

#### *2. Application of Legal Standard*

The Agency's Final Response provided insufficient information regarding the adequacy of its search. The Final Response did not specify what records were searched, by whom, and through what process. The Final Response simply states "Electronic searches were conducted for records responsive to your request" (**Attachment 3**). Therefore, ICAN cannot determine whether the Agency's search was adequate. Steinberg, 23 F.3d at 552. The Final Response simply states "Electronic searches were conducted for records responsive to your request" (**Attachment 3**). This does not satisfy the Agency's obligation under FOIA to demonstrate beyond material doubt that the search was reasonably calculated to uncover all relevant documents. Id. at 551. By omitting any detail regarding the process by which these records were searched, the agency did not satisfy this standard and did not prove that its search was adequately performed.

Further, the Agency's search was inadequate because the facts reveal a positive indication of overlooked materials. Valencia-Lucena,180 F.3d at 326. The Agency's Final Response stated that "Dr. Orenstein left the CDC in 2007, so his emails could not be searched for this request" (**Attachment 3**). However, the Agency proports to follow the email retention schedule titled GENERAL RECORDS SCHEDULE 6.1: Email and Other Electronic Messages Managed under a Capstone Approach ("GRS 6.1") propagated by the National Archives and Records Administration. Pursuant to GRS 6.1, the Agency is required to preserve Dr. Orenstein's emails permanently. The email retention schedule dictates that emails of "Capstone Officials" are to be retained permanently. Dr. Orenstein was the "Director of the US Immunization Program" from 1988-2004. Leadership roles such as these qualify an individual as a "capstone official" and therefore, his emails should be retained and searchable to produce the requested documents regardless of when he left the agency.

For these reasons, the Agency failed to conduct an adequate search for the request records. Therefore, ICAN requests the Agency conduct a search of Dr. Orenstein's correspondence and provide the records responsive to the FOIA request.

## II. APPELLATE REQUEST

Given the foregoing, ICAN hereby appeals and requests that the documents responsive to the FOIA Request be produced within 20 days of this appeal. Thank you for your time and attention to this matter. If you require any additional information, please contact us at **(240) 732-6737** or through email at **foia@sirillp.com**.

Very truly yours,

*/s/ Aaron Siri*

Aaron Siri, Esq.
745 Fifth Ave., Suite 500
New York, NY 10151

Enclosures.

# Attachment 1

Siri | Glimstad

sirillp.com | NEW YORK | LOS ANGELES | MIAMI | PHOENIX
DETROIT | AUSTIN | CHARLOTTE | WASHINGTON D.C.

**CDC FREEDOM OF INFORMATION ACT REQUEST**

**VIA ONLINE PORTAL** November 1, 2024

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

Re: *Shimabukuro and Orenstein Emails Concerning Vaccine Safety Science Article (IR#1151E)*

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("**ICAN**") and Mississippi Medical Professionals for Informed Consent ("**MMPIC**"). On behalf of ICAN and MMPIC, please provide the following records to foia@sirillp.com in electronic form:

> **All emails in which Tom Shimabukuro responded to the email provided at Attachment A; and all emails in which Walter Orenstein and/or Tom Shimabukuro forwarded the email provided at Attachment A.**

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii). ICAN is a not-for-profit news media organization whose mission is to raise public awareness about vaccine safety, other medical treatments, environmental pollutants and toxins, and overall health choices, and to provide the public with information needed in order to give informed consent. As part of its mission, ICAN actively investigates and disseminates scientifically-based health information regarding the safety of vaccines, other medical treatments, environmental pollutants and toxins, and governmental activities for free through its website,[1] a weekly health news and talk show,[2] and through press events and releases. The HighWire website has approximately 3.4 million weekly visitors. On X (formerly known as Twitter), The High Wire has approximately 190,000 followers and 1 to 2.5 million impressions in a 28-day period. On Rumble, The HighWire has approximately 83,000 followers and growing. The size of ICAN's audience and subscribers continues to grow and is illustrative of the wide public interest in the subject of health and medical safety. Critical to ICAN's mission is its proven ability to find and review critical scientific and governmental records and meaningfully report about their social impacts. One of the tools ICAN uses to gather the raw material it uses in its popular investigative reporting is the Freedom of

[1] https://www.icandecide.org/.

[2] https://thehighwire.com/.

Information Act ("**FOIA**"). ICAN is seeking the information in this FOIA request to allow it to contribute to the public understanding of government programs and any potential effects of same on public health. The information ICAN is requesting will not contribute to any commercial activities. Therefore, ICAN should be properly categorized as a media requester, and it is entitled to the search and processing privileges associated with such a category designation. Accordingly, ICAN will be forced to challenge any agency decision that categorizes it as any other category of requester.

MMPIC is a not-for profit organization comprised of medical professionals throughout the state of Mississippi. MMPIC's mission is to raise public awareness about vaccine safety, other medical treatments, and overall health choices, and to provide the public with information needed in order to give informed consent. MMPIC is seeking the information in this FOIA request to allow it to contribute to the public understanding of government programs and actions and any potential effects of those programs and actions on public health. The information MMPIC is requesting will not contribute to any commercial activities.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN and MMPIC reserve all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN and MMPIC may immediately take further administrative or legal action.

Furthermore, we specifically request that the agency provide us with an estimated date of completion for this request.

If you would like to discuss our request or any issues raised in this letter, please feel free to contact us at (240) 732-6737 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Sincerely,

*/s/ Aaron Siri*

Aaron Siri, Esq.
745 Fifth Ave., Suite 500
New York, NY 10151
foia@sirillp.com
(240) 732-6737

# Attachment A

**From:** Orenstein, Walter
**Sent:** Sun, 7 Jul 2024 15:19:36 +0000
**To:** Shimabukuro, Tom (CDC/NCIRD/ID)
**Subject:** Article coming out in the NEJM on the importance of increasing funding for vaccine safety evaluations
**Attachments:** Funding Postauthorization Vaccine-Safety Science NEJM 2024.pdf



---

Tom – I wanted to make you aware of an article published by the NEJM advocating for enhanced funding for vaccine safety.

Walt

2017. With a better understanding of the incentives that drive development of rare-disease therapies, tax incentives could be better targeted. A return to the provision of tax credits equal to 50% of clinical testing expenses may be appropriate for therapies for ultrarare diseases or those that are useful for a single rare disease, with the 25% rate being applied for all other (including secondary) orphan indications. Alternatively, tax credits could be scaled (e.g., from 25 to 50%) according to the rarity of a disease or conditioned on reasonable-pricing commitments. In all cases, direct subsidies could be clawed back once revenue exceeds $1 billion.

Because patent life now typically persists past the 7-year postapproval period, extended exclusivity has become less relevant to manufacturers and is unlikely to be a meaningful policy lever. We believe a revenue-based incentive cap and scaled tax credits hold more promise for encouraging orphan-drug development.

Many rare diseases remain understudied, and the trajectory of drug prices is increasingly unsustainable. More thoughtfully targeted incentives are therefore required to sustain advances in orphan-drug development for the next four decades.

Disclosure forms provided by the authors are available at NEJM.org.

From the Center for Health Law Studies, Saint Louis University School of Law, St. Louis (M.S.S.); Harvard Business School and the Harvard–MIT Center for Regulatory Science — both in Boston (A.D.S.); Hasso Plattner Institute, University of Potsdam, Potsdam, Germany (A.D.S.); and Duke Law School and the Duke–Margolis Center for Health Policy, Durham, NC (A.K.R.).

This article was published on July 6, 2024, at NEJM.org.

1. IQVIA Institute. Orphan drugs in the United States: rare disease innovation and cost trends through 2019. December 3, 2020 (https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/orphan-drugs-in-the-united-states-rare-disease-innovation-and-cost-trends-through-2019).
2. Bagley N, Berger B, Chandra A, Garthwaite C, Stern AD. The Orphan Drug Act at 35: observations and an outlook for the twenty-first century. Innov Policy Econ 2019;19:97-137 (https://www.journals.uchicago.edu/doi/full/10.1086/699934).
3. Miller KL, Lanthier M. Orphan drug label expansions: analysis of subsequent rare and common indication approvals. Health Aff (Millwood) 2024;43:18-26.
4. Tu SS, Nagar S, Kesselheim AS, Lu Z, Rome BN. Five-year sales for newly marketed prescription drugs with and without initial Orphan Drug Act designation. JAMA 2023;329:1607-8.
5. Beall RF, Quinn AE, Kesselheim AS, Tessema FA, Sarpatwari A. Generic competition for drugs treating rare diseases. J Law Med Ethics 2020;48:789-95.

DOI: 10.1056/NEJMp2401487


# Funding Postauthorization Vaccine-Safety Science

Daniel A. Salmon, Ph.D., M.P.H., Walter A. Orenstein, M.D., Stanley A. Plotkin, M.D., and Robert T. Chen, M.D.

The United States benefits from a robust federal immunization program that has been successful in controlling and eliminating many diseases. However, the widespread vaccine hesitancy observed during the Covid-19 pandemic suggests that the public is no longer satisfied with the traditional safety goal of simply detecting and quantifying the associated risks after a vaccine has been authorized for use. The public also wants public health authorities to mitigate and prevent rare but serious adverse reactions — which no longer seem rare when vaccines are given to millions or billions of people.

Postauthorization studies are needed to fully characterize the safety profile of a new vaccine, since prelicensure clinical trials have limited sample sizes, follow-up durations, and population heterogeneity.[1] It is critical to examine adverse events following immunization (AEFIs) that have not been detected in clinical trials, to ascertain whether they are causally or coincidentally related to vaccination. When they are caused by vaccines (vaccine adverse reactions), the risk attributable to vaccination and the biologic mechanism must be ascertained. That science becomes the basis for developing safer vaccines, if possible, and for determining contraindications to vaccination and the compensation that should be offered for AEFIs. Currently in the United States, when the Advisory Committee on Immunization Practices (ACIP) recommends a new routine vaccine, the only automatic statutory resource allocations that follow are for vaccine procurement by Vaccines for Children (VFC) and for the Vaccine Injury Compensation Program (VICP). Although the ACIP acknowledges the need,[2] there are currently no resources earmarked for postauthorization safety studies beyond annual appropriations, which must be approved by Congress each year.

**Understanding of the Biologic Mechanisms of Vaccine Adverse Reactions.***

| Year Identified | Vaccine | Vaccine Adverse Reaction | Understanding of Biologic Mechanism |
|---|---|---|---|
| 1969 | Oral polio vaccine | Vaccine-associated paralytic polio | Understood |
| 1976 | Swine influenza vaccine | Guillain–Barré syndrome | Not understood |
| 1998 | RotaShield | Intussusception | Not understood |
| 2000 | Inactivated intranasal influenza vaccine | Bell's palsy | Hypothesized but uncertain |
| 2009 | Pandemic influenza vaccine | Narcolepsy | Not understood |
| 2021 | mRNA Covid-19 vaccine | Myopericarditis | Not understood |
| 2021 | AZ–J&J Covid-19 vaccine | Thrombosis with thrombocytopenia syndrome | Hypothesized but uncertain |
| 2021 | AZ–J&J Covid-19 vaccine | Guillain–Barré syndrome | Not understood |
| 2024 | GSK–Pfizer RSV vaccine | Guillain–Barré syndrome | Not understood |

* Updated from Salmon et al.[1] AZ denotes AstraZeneca, GSK GlaxoSmithKline, J&J Johnson & Johnson, and RSV respiratory syncytial virus.

Progress in vaccine-safety science has understandably been slow — often depending on epidemiologic evidence that is delayed or is inadequate to support causal conclusions and on an understanding of biologic mechanisms that is incomplete — which has adversely affected vaccine acceptance. For example, though there were eventually more than a dozen well-conducted epidemiologic studies that led the Institute of Medicine (IOM, now the National Academy of Medicine) to conclude that measles–mumps–rubella vaccines and thimerosal in vaccines were not causing autism, the results were not available until years after these possibilities were raised publicly.[1] The slow speed of science contributed to widespread public concern and consequent decreases in immunization coverage, as well as outbreaks of measles.

In 234 reviews of various vaccines and health outcomes conducted from 1991 to 2012, the IOM found inadequate evidence to prove or disprove causation in 179 (76%) of the relationships it explored, illustrating the need for more rigorous science. In 2024, the National Academies of Sciences, Engineering, and Medicine issued a report on potential harms from Covid-19 vaccines and was unable to find sufficient evidence of a causal relationship in 65 conclusions (76%) (there was sufficient evidence in only 20 conclusions). The growing capacity of large health care databases affords new opportunities to obtain real-world data and conduct rigorous studies to quickly investigate AEFIs. The biologic mechanism remains unelucidated for most vaccine adverse reactions — notably, Guillain–Barré syndrome after administration of the 1976–1977 influenza vaccine and several other vaccines thereafter, myocarditis after mRNA-based Covid-19 vaccines, and intussusception after the first rotavirus vaccine (see table).[1] Identifying the biologic mechanisms of adverse reactions — how and in whom they occur — is critical for developing safer vaccines, preventing adverse reactions by expanding contraindications, and equitably compensating vaccinees for true adverse reactions. Recent advances in genomics, "adversomics," and understanding of the biology of adverse health outcomes have created unprecedented opportunities to elucidate the biologic mechanisms of vaccine adverse reactions.[3]

Historically, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have led postauthorization vaccine-safety surveillance and research in that they comanage the Vaccine Adverse Event Reporting System (VAERS) passive-surveillance system, which is used to detect signals that require further investigation. But though VAERS is large and events may be reported to it in a timely fashion, few VAERS reports include the specific laboratory or clinical findings required for determining

causality. In most VAERS cases, establishing a causal link would require rate calculations showing that there is a higher rate of AEFIs in vaccinated groups than in unvaccinated control groups, but VAERS reports lack much of the information needed for such calculations. Active surveillance using health care databases such as the Vaccine Safety Datalink and the FDA's Biologics Effectiveness and Safety (BEST) System managed by the CDC and the FDA has this capacity to ascertain or rule out associations between vaccines and AEFIs. Other government databases (e.g., the Medicare database) have also been used for active surveillance, and the CDC conducts clinical assessment of AEFIs by means of the Clinical Immunization Safety Assessment Network.

Over the past two decades, many new vaccines have been introduced for children and for vulnerable populations such as pregnant women and older adults. However, aside from emergency appropriations for the H1N1 influenza and Covid-19 pandemics, the budget for vaccine-safety monitoring at the CDC (which is responsible for the majority of U.S. federal efforts) has remained stagnant during this period, at about $20 million per year. Although these resources have been used efficiently, this inadequate level of funding has adversely affected the speed and completeness of the science.

Postauthorization vaccine-safety research requires adequate and timely funding directly linked to the introduction of new vaccines, just as VFC and VICP funding is. The VICP is funded by an excise tax on each dose of routinely recommended vaccines ($0.75 per case of disease prevented), which goes to the VICP Trust Fund. Trust fund income has exceeded expenditures by about $120 million per year since 1991, and there was a balance of $4.3 billion as of April 30, 2023. Using this balance for vaccine-safety science and reduction of vaccine reactions would benefit immunization programs and the public, in keeping with the VICP's intent.

During the 5 years of legislative hearings that led to the VICP, Senator Paula Hawkins (R-FL), its sponsor, noted, "Although compensation of the injured children is a key component . . . other provisions of this bill are of equal importance, perhaps more important, because they are designed to improve the entire immunization program to prevent the injuries in the first place."[4] Furthermore, as explained by Senate Bill 827, passed by the Senate Labor and Commerce Committee in August 1986 but never enacted, this activity is a federal (not an industry) responsibility, "because communicable diseases are a national problem, because the primary thrust for childhood vaccination programs has come from the Federal Government, and because childhood vaccine-related injuries which may tend to undermine the public's confidence in these vaccination programs are a national concern."[5]

***Postauthorization vaccine-safety research requires adequate and timely funding directly linked to the introduction of new vaccines, just as Vaccines for Children and Vaccine Injury Compensation Program funding is.***

Though the clear intent of the law creating the VICP included improving vaccine-safety monitoring and reducing vaccine injuries, the funding to implement it was established by a separate tax code, which permits funds to be used only for payment of compensation and administrative costs of operating the compensation program — not for vaccine-safety monitoring and science. This omission may have been somewhat understandable in 1986, when capacity for safety monitoring and science were less mature, but they have since evolved.

We propose amending the VICP tax code to link funding for vaccine-safety monitoring with vaccine usage. Doing so would not interfere with existing funding for vaccine-injury compensation, since the program has always run a substantial surplus, using only about a third of available funds. Thus, a budget-neutral path is feasible even if the remaining funds are used for vaccine-safety research conducted both within and outside of federal agencies and departments. Expanded activities could include capacity building, epidemiologic studies, and investi-

gations (including genomic studies) of the biologic mechanisms of adverse reactions. A research agenda could be developed to focus efforts on meeting the needs of federal agencies, the medical and public health communities, and the public. The independent National Academies of Sciences, Engineering, and Medicine could be charged with reviewing the vaccine-safety system and recommending the optimal structure and governance for an adequately funded system. Allowing the use of a portion of the existing federal excise tax to fund vaccine-safety research would ensure that the United States has the surveillance, science, and rapid-response capacity to both detect and prevent vaccine injuries. This long-overdue action would be an important step toward rebuilding public confidence in the immunization system.

Disclosure forms provided by the authors are available at NEJM.org.

From the Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health, Baltimore (D.A.S.); Emory University, Atlanta (W.O.); the University of Pennsylvania, Philadelphia (S.A.P.); and the Brighton Collaboration, Task Force for Global Health, Decatur, GA (R.T.C.).

This article was published on July 6, 2024, at NEJM.org.

1. Salmon DA, Chen RT, Black S, Sharfstein J. Lessons learned from COVID-19, H1N1, and routine vaccine pharmacovigilance in the United States: a path to a more robust vaccine safety program. Expert Opin Drug Saf 2024;23:161-75.
2. Oliver SE, Gargano JW, Marin M, et al. The Advisory Committee on Immunization Practices' interim recommendation for use of Pfizer-BioNTech COVID-19 vaccine - United States, December 2020. MMWR Morb Mortal Wkly Rep 2020;69:1922-4.
3. Top KA, Chen RT, Levy O, et al. Advancing the science of vaccine safety during the coronavirus disease 2019 (COVID-19) pandemic and beyond: launching an International Network of Special Immunization Services. Clin Infect Dis 2022;75:S11-S17.
4. United States Senate. National Childhood Vaccine-Injury Compensation Act Hearing (S2117). Committee on Labor and Human Resources. 98th Congress; Second Session. Washington DC: U.S. Government Printing Office; May 3, 1984 (https://files.eric.ed.gov/fulltext/ED255480.pdf).
5. National Childhood Vaccine Improvement Act of 1986, S. Rep. no. 483, 99th Cong., 2d Sess. (1985-1986).

DOI: 10.1056/NEJMp2402379


# On Her Own Two Feet

Michael A. Incze, M.D., M.S.Ed., and Laura Stolebarger, B.S.N.

It was 13 minutes past the start of her appointment, and we were getting worried that Ms. S. wouldn't show. We were accustomed to waiting; in the past, Ms. S. had often been hours late to her visits. Of course, once one had seen the hill she had to climb in her wheelchair to get to our clinic — often in snow or broiling heat — any twinge of annoyance at her tardiness would vanish. Today was different, though. For the first time in the 4 years we had known her, we expected Ms. S. to walk through the door.

We first met Ms. S. in 2019, just weeks after she had a below-the-knee amputation because of osteomyelitis, most likely stemming from injection-drug use. At our first visit, her proximal goal was clear: to get out of the wheelchair she had been relying on since discharge and start walking again. Working together as patient and primary care team, we quickly got her established with a rehabilitation specialist and fit for a prosthesis. She was seeing us regularly for buprenorphine treatment of her opioid use disorder as well. But after a couple of visits with a physical therapist, she was having trouble. Her opposite knee was so arthritic that she couldn't walk with the prosthesis. We referred her to an orthopedist who said the knee needed to be replaced. There was just one catch: she would have to be abstinent from all illicit drugs for a year before he would consider operating.

Unable to find any evidence to support this stipulation, we first inquired about it and then pleaded with the surgeon for a meeting to discuss his rationale and openness to a more patient-centered plan. He was concerned about the increased risk of postoperative complications given the patient's history of injection-drug use,[1] and despite the fact that Ms. S. had been actively engaged in addiction treatment for nearly 3 months, the surgery would have to be deferred. The news was a crushing blow for our patient. Facing the reality of a year confined to a wheelchair, she gave up. Her substance use spiraled, she stopped engaging with her specialists altogether, and we never saw her prosthesis again.

For the next 3 years, Ms. S. was stuck in a pattern of erratic substance use, depression, and pain. Through all that adversity, and despite the stigma she encountered regularly in health care settings, she still came to see us in

# Attachment 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

November 4, 2024

Aaron Siri
Attorney, Siri & Glimstad LLP
745 Fifth Ave., Suite 500
New York, NY 10151
Via email: foia@sirillp.com

Dear Mr. Siri:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your Freedom of Information Act (FOIA) request dated November 1, 2024 for:

> *[IR#1151E] All emails in which Tom Shimabukuro responded to the email provided at Attachment A; and all emails in which Walter Orenstein and/or Tom Shimabukuro forwarded the email provided at Attachment A.*

Your request was assigned #25-00165-FOIAand placed in our complex processing queue.

**Extension of Time**
In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request.

We will require an additional ten-working-days to respond to your request because:
X We reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request Rachel Friend at ult5@cdc.gov or (404) 639-4958 or our FOIA Public Liaison, Roger Andoh at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

**Fees and Fee Waivers**
You requested that we waive fees associated with processing your request. Your request is granted.

**Fee Category**

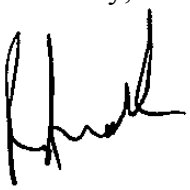
Because you are considered a "News Media requester," you will not be charged fees unless you choose to receive responsive records in hard copy. (10 cents/page)

**Cut-off-date**
If you don't provide us with a date range for your request, the cut-off date for your request will be the date the search for responsive records starts.

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number. If you have any questions regarding your request, please contact Rachel Friend at ult5@cdc.gov or (404) 639-4958.

We reasonably anticipate that you should receive a final response by December 15, 2024. Please know that this date roughly estimates how long it will take the agency to close requests ahead of your request in the queue and complete work on your request. The actual date of completion might be before or after this estimated date.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

25-00165-FOIA

# Attachment 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

November 5, 2024

Aaron Siri
Attorney, Siri & Glimstad LLP
745 Fifth Ave., Suite 500
New York, NY 10151
Via email: foia@sirillp.com

Dear Mr. Siri:

This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of November 1, 2024, for

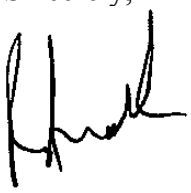
> *[IR#1151E] All emails in which Tom Shimabukuro responded to the email provided at Attachment A; and all emails in which Walter Orenstein and/or Tom Shimabukuro forwarded the email provided at Attachment A.*

Electronic searches were conducted for records responsive to your request. A search of our records failed to reveal any documents pertaining to your request. Additionally, Dr. Orenstein left CDC in 2007, so his emails could not be searched for this request, nor would they have been responsive, given the timeline of your request.

You may contact our FOIA Public Liaison at 770-488-6246 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be electronically transmitted by February 3, 2025.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer

Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

#25-00165-FOIA